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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,285	05/29/2001	Frank Pipers	408.015A	6237

7590 03/26/2003

Bierman, Muserlian and Lucas  
600 Third Avenue  
New York, NY 10016

EXAMINER

COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/867,285

Applicant(s)

PIPERS, FRANK

Examiner

Rebecca Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 12/18/02 and 12/24/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19, 21-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No support is seen in the specification for the recitation "basic agent" and applicant has not pointed out where support may be found.

Claims 12, 21-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 12, 21 and 27 it is not clear how the terms "training, transportation, change in environment or pregnancy" differ over "stress," since all of the terms describe stressful situations. Amending the claim to recite "during periods of stress selected from the group consisting of training, transportation, change in environment and pregnancy" will overcome this rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19, 21-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over FDA Federal Register (FDA), Papich or WO 96/31213, alone or in combination.

FDA (summary) discloses that omeprazole is used to prevent gastric ulcers in horses.

Papich (abstract, pp 502-504, Table I) discloses that omeprazole is used to prevent gastric ulcers in small animals, including dogs.

WO 96/31213 (pages 1-7) discloses that compositions comprising proton pump inhibitor (PPI), including the composition of claim 10 and recited dosage, and that they are used to treat gastric ulcers.

Claim 21 and some dependent claims differ over the references in reciting administration prior to or during conditions of stress. Other dependent claims differ over the references in frequency and route of administration, formulation and human administration. However, in view of the FDA disclosure to use omeprazole to prevent gastric ulcers in horses and Papich's disclosure to use antiulcer drugs for the prevention of gastric ulcers in small animals, that ulcers are associated with stressful conditions and that omeprazole is used for ulcers, it would be obvious to one of ordinary skill to administer omeprazole to mammals including, horses and small animals to prevent gastric ulcers associated with stressful conditions.

Additionally, it would be obvious to one of ordinary skill in the art that a compound that is taught to be useful to prevent gastric ulcer in a horse or dog would also be useful to prevent gastric ulcer in a human, since WO 96/61213 discloses that PPIs are used in humans and animals to treat gastric ulcers in humans and animals.

Furthermore, WO 96/61213 discloses the instant frequency, route of administration and formulation.

Applicant's argument that Papich deals only with small animals is not persuasive, since claim 21 includes small animals. Applicant's argument that the prevention is

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referred to only where the animal is predisposed is not persuasive, since Papich discloses situations that include those disclosed in the instant specification and recited in the instant claims, including in claim 21 to a "mammal in need thereof during periods of stress." Furthermore, FDA discloses using omeprazole to prevent gastric ulcers in horses.

Applicant's argue that Papich does not teach its use for preventing ulcers in horses. However, FDA discloses that omeprazole is used to prevent omeprazole in horses. Furthermore, independent claim 21 recites "a mammal" and its dependent claim 3 recites "dog."

Applicant's argument that WO 96/31213 deals with the treatment of ulcer disease and has nothing to do with prevention is not persuasive, since WO 96/31213 was cited to show that that the instant compositions and dosages are known.

It is noted that the rejection over FDA was not argued.

It is not clear why Melnichouk et al was argued.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
REBECCA COOK  
PRIMARY EXAMINER  
GROUP 1200/1614

March 20, 2003